K082587

510(k) Summary

NOV 14 2008

Submitter Name:	MEDX, Inc.
Submitter Address:	3456 N. Ridge Avenue, Suite 100 Arlington Heights, IL 60004
Establishment Reg. #:	1419459
Phone Number:	847.463.2020
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Contact Person:	Eric Ellingson
Date Prepared:	02 September 2008
Device Trade Name:	C-Quest System
Common Name	Cardiac Gamma Camera System
Classification Name, Number & Product Code:	Emission Computed Tomography System 892.1200 KPS
Predicate Devices:	Cardiocam
Device Description and Statement of Intended Use	Device Description: A compact, dual-head dedicated cardiac camera system comprised of a gantry supporting a fixed 90 degree dual head detector and a patient table. The C-Quest system is operated through interaction with an acquisition and processing computer system (NuQuest) or dedicated handheld controller or touch screen. Statement of Intended Use: C-Quest equipped with NuQuest (hereinafter referred to as C-Quest system) forms an emission computed tomography system intended to detect the location and distribution of gamma-ray emission radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. C-Quest system is primarily intended for cardiac applications, however the C-Quest system design also supports non-cardiac procedures of the patient's chest region and body extremities
Summary of Technological	The C-Quest cardiology scintillation camera design comprises an open gantry supporting a fixed 90 degree dual head detector and a patient table. C-Quest is operated through interaction with an acquisition and

Characteristics	processing computer system (NuQuest), or the C-Quest's dedicated handheld controller or touch screen. The patient table can perform vertical and horizontal (along long axis) motor-driven movement for patient positioning. Tomographic studies can be performed in a circular or elliptical orbit with or without gating. Each detector head consists of a rectangular NaI(Tl) crystal, photo-multiplier tubes (PMTs) and the detector electronics. Planar static and dynamic studies can be performed. The C-Quest system supports gamma-ray emission radionuclides within the energy range of 60 - 170 keV.
Conclusion	The information discussed above demonstrates that C-Quest system performs as well as the predicate device
Declarations	This summary includes only information that is also covered in the body of the 510(k). This summary does not contain any puffery or unsubstantiated labeling claims. This summary does not contain any raw data, i.e., contains only summary data. This summary does not contain any trade secret or confidential commercial information. This summary does not contain any patient identification information

Summary of Technical Characteristics

Feature	C-Quest	Cardiocam
510(k) Number		K011611
Manufacturer	MEDX	DANISH DIAGNOSTIC DEVELOPMENT A/S
Classification # & Product Code	KPS 892.1200 Emission computed tomography system	KPS 892.1200 Emission computed tomography system
Intended Use	The C-Quest system is a dual head system designed to acquire data for cardiac multi-slice images. The system is intended for use as a diagnostic imaging device. When used with the appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in the body. The system allows you to acquire data from high resolution three dimensional, static, gated or dynamic imaged of biochemical and metabolic processes using approved radionuclides within the range of 60 – 170 keV such asTc-99m, TI-201, or Co-57.	The Cardiocam system is a dual head system designed to acquire data for cardiac multi-slice images. The system is intended for use as a diagnostic imaging device. When used with the appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in the body. The system allows you to acquire data from high resolution three dimensional, static, gated or dynamic imaged of biochemical and metabolic processes using Tc-99m, Ti-201, or Co-57.
Mode of Action	Image acquisition of radioactive nucleotide distribution by scintillation cameras	Image acquisition of radioactive nucleotide distribution by scintillation cameras
Design	Open gantry supporting a fixed 90 degree dual head detector and a patient table	Open gantry supporting a fixed 90 degree dual head detector and a patient table
Method of Operation	Operated through interaction with an acquisition and processing computer system	Operated through interaction with an acquisition and processing computer system
Intrinsic spatial resolution – Center FOV	FWHM: ≤3.5mm FWTM: ≤7.4mm	FWHM: ≤2.8mm FWTM: ≤2.9mm
Intrinsic spatial resolution – Useful FOV	FWHM: ≤3.7mm FWTM: ≤7.6mm	FWHM: ≤5.4mm FWTM: ≤5.6mm
Intrinsic Spatial Linearity - Center FOV	Differential: ≤0.4mm Integral: ≤0.8mm	Differential: 0.18mm Integral 0.38mm
Intrinsic Spatial Linearity - Useful FOV	Differential: ≤0.5mm Integral: ≤1.0mm	Differential: 0.20mm Integral: 0.40mm
Intrinsic Uniformity - Center FOV	Integral: +/- 2.5% Differential: +/- 1.5%	Integral: +/- 2.4% Differential: +/- 1.9%
Intrinsic Uniformity - Useful FOV	Integral: +/- 3.0% Differential: +/- 2.0%	Integral: +/- 2.9% Differential: +/- 2.4%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDX, Inc.
% Mr. William Greenrose
President & CEO
Qserve America, Inc.
220 River Road
CLAREMONT NH 03743

NOV 14 2008

Re: K082581
Trade/Device Name: C-Quest
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: September 2, 2008
Received: September 5, 2008

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.1 Indications for Use Statement

510(k) Number (if known): K082581

Device Name: C-Quest

Indications for Use:

The C-Quest system is a dual head system designed to acquire data for cardiac multi-slice images. The system is intended for use as a diagnostic imaging device. When used with the appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in the body. The system allows you to acquire data from high resolution three dimensional, static, gated or dynamic images of biochemical and metabolic processes using approved radionuclides within the energy range of 60 – 170 keV such as Tc-99m or Tl-201.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082581